IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/634,642	Confirmation No.: 7193
Applicant	:	William Suttle Peters, et al.	
Filing Date	:	August 4, 2003	
Title	:	Intraluminal Inflatable Counter-Pulsation Heart Assist Device	
Group Art Unit	:	3762	
Examiner	:	Alyssa M. Alter	
Docket No.	:	13634.4003	
Customer No.	:	34313	

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AMENDED APPEAL BRIEF AND REQUEST FOR ORAL HEARING

Sir:

In response to the Notice dated June 13, 2007, which indicated that Applicant's initial brief filed on April 5, 2007 was not in compliance with 37 CFR § 41.37(c), Applicant files herewith an Amended Appeal Brief. In this amended appeal brief, Applicant believes that he has amended the appeal brief in a manner which complies with ¶¶s 4 and 10 of the Notice dated June 13, 2007. With regard to items 8 and 9, Applicant respectfully points out that he does not rely on any evidence submitted under 37 CFR §§ 1.130, 1.131 or 1.132 and, in fact, has not submitted any such evidence. With regard to numbered paragraph 9, Applicant respectfully points out that his original appeal brief stated that "there are no known related appeals or interferences" and that, therefore, there are no copies of any decisions in related appeals.

Real Party in Interest

Sunshine Heart Company Pty Ltd of Australia is the real party in interest.

Related Appeals and Interferences

There are no known related appeals or interferences.

Status of Claims

Claims 1-17 and 19-32 are pending in this application. These claims have all been rejected and are the claims on appeal. Claim 18 has been cancelled.

Status of Amendments

An Amendment filed on September 28, 2006 has been entered for the purpose of appeal and overcomes the rejections based on 35 U.S.C. 112, first and second paragraphs made in the final rejection dated August 18, 2006.

Summary of Claimed Subject Matter

There are three independent claims, which are apparatus claims 1 and 30, and claim 23, a method claim. Reference to the drawings are shown in parentheses

Claim 1 is directed to a heart assist device (10) which can be placed in a blood vessel such as an artery (22) and comprises an inflatable member (14) which can be alternately inflated and deflated to create a pumping action to assist the pumping action of the heart. The device comprises a balloon (14) which can be moved between an inflated condition and a deflated condition and a shell (12) to which the balloon is attached. The shell is adapted to hold the device in place inside a blood vessel and adjacent to an inside surface of the blood vessel. In its deflated condition, the balloon lies closely adjacent to the wall of the shell and in the inflated condition, the balloon projects into the vessel from the wall.

Claim 30 is directed to a heart assisted device (10) comprising an intraluminal inflatable balloon (14) which is attached to a shell (12) which is adapted to be located adjacent to the surface of an inner wall of an arterial vessel, the shell (12) having an arcuate cross section (as shown in Figure 2) the interior surface of balloon (14) facing the concave surface of the shell and the shell having a port (18) in its wall to permit fluid flow in a direction transverse to the direction of the flow of blood through the vessel and the port being connected to a tube (30).

The apparatus of claim 1 is described in the specification at page 4, line 27 - page 5, line 10. Claim 30 is described at page 1, line 27 - page 5, line 10, page 5, lines 26-30 and at page 6, lines 1-6.

Method claim 23 comprises placing the heart assist device (10) against the inner surface of the wall of a blood vessel, connecting the inflatable balloon (14) to a fluid pressure source (26), and energizing the fluid pressure source to expand and contract the balloon which such expansion and contraction being in counter-pulsation with the heart of the patient. The method of claim 23 is described at page 3, lines 26-32, and page 4, line 27 - page 5, line 10.

The device is best shown in Figures 1 and 4, wherein the shell is denoted by numeral 12 and the balloon by numeral 14. The device and its operation are described at pages 4-6 of the specification.

Grounds of Rejection To Be Reviewed on Appeal

Claims 1-11, 13, 16-17, 23-26 and 28-31 have been rejected as obvious under Section 103 over Dobak Patent No. 5,827,171 in view of Bley Patent No. 5,674,241. Claims 1-17, 23-26 and 28-31 stand rejected as anticipated by Dobak Patent No. 5,820,542 in view of Bley Patent No. 5,674,241. Claims 21, 22 and 27 have been rejected as unpatentable over Dobak Patent No. 5,827,171 or Dobak Patent No.

5,820,542 under Section 103. Claims 19 and 20 have been rejected as unpatentable under Section 103 over Dobak Patent No. 5,827,171 or Dobak Patent No. 5,820,542 in view of Lederman Patent No. 6,210,318. Claims 13, 14 and 32 have been rejected as unpatentable under Section 103 over Dobak Patent No. 5,827,171 or Dobak Patent No. 5,820,542.

Reason Why This Appeal Should Be Remanded To The Examiner For Consideration Of Additional Prior Art

As stated in Applicant's Information Disclosure Statement filed on October 27, 2006, Applicant believes Freed Patent No. 6,471,633 to be more pertinent to the claimed invention than any of the prior art relied upon by the Examiner. In that Information Disclosure Statement, Applicant stated:

> Applicant requests that the final rejection currently in effect in the present application be vacated and that the prosecution proceed on the basis of the Freed patent.

This request has gone unheeded and is believed to create a situation in which it would be a waste of time for this appeal to go forward. However, this situation can be remedied by a remand of this application to the Examiner for the purpose of considering the Freed patent and such remand is respectfully requested.

Argument

All of the claims of the present application are directed to an uncomplicated device and its use. The device, as noted above, comprises a shell which can be placed adjacent to the inner wall of a blood vessel such as an artery and a balloon attached to the shell which is inflatable and deflatable

and can function as a heart assist device. In other words, the inflation and deflation of the balloon, as recited in the method claims, in counter-pulsation with the heart create a pumping action which assists the pumping of the heart.

Claims 1-11, 13, 14, 16, 17, 23-26 and 28-30 have been rejected as anticipated by Dobak '171. Claim 1 recites that the balloon is attached to a shell which is adapted to hold it adjacent to the inside surface of a wall of an arterial vessel such that in the deflated condition, substantially the whole of the balloon lies closely adjacent to the wall of the vessel and, in the inflated condition, the balloon projects into said vessel from said wall.

The device of Dobak '171 is fundamentally different from that recited in the claim. There is no shell in the device of Dobak '171 which simply discloses an expandable device having an inner and an outer balloon with the outer balloon encapsulating a stent which holds the outer balloon at the desired diameter. The device is then placed in a blood vessel such that the balloons are coaxial with the vessel and control fluid is pumped into and evacuated from the space between the balloons. An axially located port is provided to permit blood to flow into the inner balloon and then be forced out in a direction opposite to the direction in which it entered the inner balloon when the inner balloon is contracted by the pumping of fluid into the space between the inner and outer balloons. Thus, the device of Dobak '171 provides in-and-out flow blood. In this regard, Applicants note that the Examiner has taken the view that a third balloon, element 18, which is shown in some of the embodiments of Dobak '171 corresponds to the "shell" of the present invention. However, outer balloon 18 is not a shell and has a function completely different from the shell recited in the rejected claims. As disclosed at column 5, lines 14 and 15, Dobak '171 plainly says:

"In some embodiments, a protective balloon 18 is not required."

Dobak '171 goes on to say, at column 5, lines 16-19 that:

> "The balloons 14, 16, 18 are made of a flexible material which can expand up to a desired size, or diameter, after which the material essentially does not expand further, even if the pressure inside the balloon is increased further."

The shell recited in the claims of the present application is incapable of expansion. To more fully bring out this distinction, claim 1 has also been amended to recite that the shell is non-expandable. As may clearly be seen from Figure 2 of the present application, it is only the balloon or chamber which expands when inflated.

With regard to claims 3, 24 and 29, the stent of Dobak '171 is attached to balloon 16, but not to balloon 14. Plainly, balloon 14 is compressed and expanded without any movement of stent 20 located in and attached to balloon 18. Thus, balloon 14 cannot be said to be attached or to be coupled to stent 20.

Claims 4-9 are patentable for the same reasons as claims 1-3. Dobak '171 does not disclose a stent covered with a fabric as recited in claim 10. The stent of Dobak '171 cannot be covered with a fabric because the stent is buried in balloon 16. In contrast, the stent of the present invention and of claim 10 can be covered with a fabric because the stent presents an exposed surface which the stent of Dobak '171 is incapable of doing. The same analysis applies to claim 11 because the balloon 16 of Dobak '171 prevents any coating from being applied to his stent.

With regard to claims 13 and 14, claim 13 makes it clear that when the balloon of the present invention extends around the full circumference of the lumen of the stent frame, there is substantially no space between them. Claim 14 recites that the balloon or chamber extends around only a portion of the circumference of the stent. Neither feature is shown in Dobak.

Claims 16 and 17 are patentable for the same reasons as the claims upon which they depend. Claims 23 and 30 are fundamentally different from the teachings of Dobak '171 and the portion of Dobak '171 quoted in the rejection has no relevance to these claims. For the reasons stated above, Dobak '171 completely fails to disclose the shell recited in these claims and does not disclose that the balloon is expanded away from the shell and contracted toward the shell such that when deflated, it is adjacent to the inner wall of the vessel.

With regard to claim 26, the rejection based on Dobak '171 is plainly misplaced. The entire device of Dobak '171 is deployed intraluminally whereas claim 6 recites deploying the fluid pressure source by forming an aperture in the wall of the aorta or other artery and connecting a fluid conducting tube from the fluid pressure source to the balloon or chamber. Dobak '171 does not disclose the formation of such an aperture and, given the construction of the Dobak '171 device, the formation of such an aperture would be severely harmful to the patient because the patient would lose blood through the aperture.

The rejection of claim 28 over Dobak '171 is also plainly misplaced. This claim recites that the balloon prevents blood from flowing over the surface of the shell which was plainly intended by the original language. As previously noted, there is no shell disclosed in Dobak '171 and protective balloon 18 is simply another balloon and not a non-expandable shell.

Claims 1-17, 23-26 and 28-30 have been rejected as anticipated by Dobak '542. It is noted that the rejections of claims 1-11, 13, 14, 16, 17, 23-26 and 28-30 are identical to the rejections based on Dobak '171. Thus, the discussion regarding the rejection of these claims based on Dobak '171 is equally pertinent to the rejection of these claims over Dobak '542 because the relevant disclosures of the two Dobak patents are identical.

Claims 21, 22 and 27 have been rejected as obvious over both of Dobak '171 and Dobak '542. Given the construction of the Dobak device, it would be impossible to place the stent intraluminally and then connect it to a fluid pressure source placed in the right chest through a sternotomy because the pressure source of Dobak must be intraluminal. In other words, the several balloons of Dobak are inflated by pressure lumens internal to the catheter and it would simply be impossible to connect a pressure source for the balloons of Dobak in an external manner after a sternotomy. Figure 4 of the present application illustrates the manner in which a pressure source is connected to the balloon of the present invention. As shown in this embodiment, tube 18 communicates with space 16 inside of balloon 14 by transversely connecting with shell 12. Such a deployment is so fundamentally different from Dobak that Dobak cannot be considered to suggest it. Similarly, the performance of an aortotomy is completely at odds with the deployment of the device of Dobak for the same reasons as those expressed with regard to claim 21. Still again, claim 27 recites a sternotomy and is fundamentally different from Dobak for the same reasons as claim 22.

Claims 19 and 20 are rejected as obvious over Dobak '171 or Dobak '542 in view of Lederman. Claims 19-20 are patentable for the reasons expressed with regard to the claims from which they depend. Furthermore, claim 19 recites that the gas carrying tube exits the body percutaneously and claim 20 recites that the fluid carrying tube is connected to a port thoracoscopically. For the reasons stated with regard to claims 21, 22 and 27, the connections recited in claims 19 and 20 could not possibly be made with the device or deployment method of Dobak which are confined to intraluminal deployment of the tube. Lederman does not remedy any of the deficiencies of the Dobak patents.

The balloon of Lederman is not attached to anything and claims 1-18 and 20-31 recite that it is "separately positionable with respect to said stent." Thus, it is plain that Lederman desires freedom of movement between the balloon and the stent. In sharp contrast, claim 1, upon which claims 19 and 20 depend, recites that the balloon is attached to a shell. No such structure can be found in the system of Lederman because:

1. Lederman does not disclose a shell of any kind.
2. Lederman does not disclose a balloon attached to a shell.
3. It is contrary to the teaching of letter for the balloon to be attached to a stent.

Furthermore, claims 19 and 20 recite a device wherein the inflation tube for the balloon is connected to the balloon by forming an aperture in the aorta or other artery after the balloon in installed. Thus, the inflation tube will be a short length tube and not the long-length catheter disclosed by Lederman as being the inflation tube. The short length tube installed in this manner is more conducive to permitting the heart assist device to remain in place for an extended period of time than the long-length catheter of Lederman. The Examiner's assertion that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the fluid as taught by Dobak III, et al. with a gas as taught by Lederman, since both fluids facilitate the inflation and deflation of the pumping balloon has no significance. In fact, this statement has nothing to do with the profound deficiencies of Lederman as a reference and has no basis in the record.

There is no suggestion or motivation in the references of record or in the relevant art generally for combining Lederman with either Dobak patents. The Dobak patents have stent 20

encapsulated by the outer balloon 16 whereas the stent and balloon of Lederman must be maintained as separate elements.

Claims 13, 14 and 32 have been rejected under Section 103 as being unpatentable over Dobak '171 or Dobak '542. The Examiner states, entirely incorrectly, that the Dobak patents disclosed the claimed invention and goes on to say that the Dobak patents do "not disclose expressly the balloon or chamber extending around only a portion of the circumference, instead of the entire circumference." Then, on the basis of absolutely nothing, states that this feature would be obvious. First, it is pointed out that claim 13 does not recite this feature and that the rejection of claim 13 is badly misplaced. Second, the partial extension around the full circumference of the lumen of the frame recited in claim 14 provides a freedom of movement as between the balloon and frame which is impossible for the structure of the Dobak patents to achieve because the stent of Dobak is buried in outer balloon 16.

Conclusion

Remand

Applicant repeats his request that this appeal be remanded so that the Examiner can consider the Freed patent which is plainly more pertinent than the prior art involved in the present appeal.

With regard to the prior art of record, it is remarkably remote and does not constitute a proper basis for the rejection of the appealed claims. Thus, reversal of these rejections is respectfully requested.

Request for Oral Hearing

Applicant hereby requests that an Oral Hearing be scheduled in this application. The Commissioner is hereby authorized to charge any fees associated to Deposit Account No. 15-0665.

Fees

The Commissioner is authorized to charge Orrick's Deposit Account No. **15-0665** for any fees required and credit any overpayments to said Deposit Account No. **15-0665**.

Respectfully submitted,

Orrick, Herrington & Sutcliffe, LLP

Dated: June 26, 2007

By: _____
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APPENDIX

1. A heart assist device comprising:

an intraluminal inflatable counter-pulsation balloon, or chamber which can be moved between an inflated condition and a deflated condition; and

said balloon or chamber being attached to a shell which is adapted to hold it in place adjacent to the inside surface of wall of an arterial vessel, such that, in the deflated condition, substantially the whole of the balloon or chamber lies closely adjacent to said wall and, in the inflated condition, the balloon or chamber projects into said vessel from said wall.

2. The heart assist device as claimed in claim 1, wherein the balloon or chamber is coupled to a stent having an expandable frame.

3. The heart assist device as claimed in claim 2, wherein the counter-pulsation balloon or chamber is attached to a portion of the inner wall of the frame.

4. The heart assist device as claimed in claim 2, wherein the frame of the stent is self expanding.

5. The heart assist device as claimed in claim 4, wherein the frame is formed of a spring material.

6. The heart assist device as claimed in claim 2, wherein the frame is formed of a shape memory alloy.

7. The heart assist device as claimed in claim 2, wherein the frame is balloon or chamber expandable.

8. The heart assist device as claimed in claim 2, wherein the stent, together with the balloon or chamber coupled thereto, is packaged into a catheter delivery structure which can be introduced into a suitable artery.

9. The heart assist device as claimed in claim 2, wherein the frame of the stent is formed of wires.

10. The heart assist device as claimed in claim 9, wherein the frame is covered with a fabric.

11. The heart assist device as claimed in claim 9, wherein the frame has a coating around its periphery on either the outside or the inside of the frame.

12. The heart assist device as claimed in claim 9, wherein the wires of the stent frame are bare adjacent any vessels branching off from a vessel into which the stent is placed.

13. The heart assist device as claimed in claim 2, wherein the frame defines a lumen and the balloon or chamber extends around the full circumference of the lumen of the frame, such that there is substantially no space between them.

14. The heart assist device as claimed in claim 2, wherein the frame defines a lumen and the balloon or chamber does not extends around the full circumference of the lumen of the frame, but only a portion thereof.

15. The heart assist device as claimed in claim 14, wherein the part of the stent over which the balloon or chamber does not extend are formed as a bare stent so that any branch vessels diverging from the artery in which the stent is positioned will not be occluded.

16. The heart assist device as claimed in claim 1, further including a fluid conducting tube communicating with the interior of the balloon or chamber.

17. The heart assist device as claimed in claim 16, further including a fluid pressure source connected to the balloon or chamber via the fluid conducting tube, the fluid pressure source adapted to cause the inflatable balloon or chamber to be expanded and contracted in counter-pulsation with the heart of a patient into whom the balloon or chamber has been placed.

19. The heart assist device as claimed in claim 17, wherein the fluid conducting tube is a gas carrying tube which is adapted to exits the body percutaneously.

20. The method as claimed in claim 26, wherein the fluid carrying tube is connected to a port on the stent thoracoscopically.

21. The method as claimed in claim 23, wherein the stent is placed intraluminally and then connected to a fluid pressure source placed in the right chest through a sternotomy.

22. The method as claimed in claim 26,, further including a liquid carrying tube is connected through an aortotomy to a port on the shell which is in communication with the interior of the balloon or chamber.

23. A method of assisting the functioning of a heart of a patient, the method including the steps of:

holding a shell having a heart assist device attached thereto, said heart assist device comprising an intraluminal inflatable counter-pulsation balloon, or chamber, in place against the inner surface of a wall of an arterial vessel of the patient;

connecting the inflatable balloon or chamber to a fluid pressure source;

energizing the fluid pressure source to expand said balloon or chamber away from the wall of said shell and to contract the inflatable balloon or chamber such that it is placed adjacent to

the inside of the wall of said shell, such expansion and contraction being in counter-pulsation with the heart of a patient into whom the balloon or chamber has been placed.

24. The method as claimed in claim 23, wherein the chamber or balloon is coupled to a stent comprising an expandable frame and the method includes the step of attaching the counter-pulsation balloon or chamber to the inside wall of the shell.

25. The method as claimed in claim 23, wherein the method also includes the step of packaging the stent, together with the balloon or chamber, into a catheter delivery structure and introducing the structure into a suitable artery.

26. The method as claimed in claim 23, wherein the method also includes the step of placing the stent intraluminally and then connecting the balloon or chamber to a fluid pressure source by forming an aperture in the wall of the aorta or other artery and connecting a fluid conducting tube from the fluid pressure source to the balloon or chamber.

27. The method as claimed in claim 23 wherein, the method also includes the step of placing the stent intraluminally and then connecting it to a hydraulic driver placed in the right chest through a sternotomy.

28. The heart assist device as claimed in claim 1, wherein the balloon or chamber prevents blood from flowing over the surface of the shell which is adapted to be held against the inner wall of an arterial vessel.

29. The heart assist device of claim 1, wherein the balloon or chamber is adapted to lie adjacent to the inner wall of the shell when the balloon or chamber is deflated.

30. A heart assist device comprising:

an intraluminal inflatable counterpulsation balloon or chamber;

said balloon or chamber being attached to a shell which is adapted to be located adjacent to the surface of an inner wall of an arterial vessel, said shell having an arcuate cross-section, the interior surface of said balloon or chamber facing the concave surface of said shell, said shell having a port in its wall to permit fluid flow into said balloon or chamber in a direction transverse to the direction of flow of blood through the vessel and said port being connected to a tube.

31. The heart assist device of claim 30 wherein an expandable stent having a lumen is coupled to said balloon or chamber.

32. The heart assist device of claim 31 wherein the balloon or chamber does not extend around the full circumference of the lumen of the stent, but only extend around a part of the circumference of the lumen of the stent.